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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/311,689	05/13/1999	ARAGULA GURURAJ RAO	0571R2	1556

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EXAMINER

KERR, KATHLEEN M

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 04/10/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/311,689

Applicant(s)

RAO ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 12 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 9-25, 28-31, 54-59, 61, 63-67, 69-72, 76-87 and 96-99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 9-12, 14-19, 21-23, 25, 28-31, 54-59, 61, 63-67, 69, 70, 72, 76-85, 87, 96 and 97 is/are allowed.
- 6) ☒ Claim(s) 98 and 99 is/are rejected.
- 7) ☐ Claim(s) 13, 20, 24, 71 and 86 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-Final rejection (Paper No. 27 mailed on November 12, 2002), Applicants filed an amendment and response (Paper No. 28 received on February 12, 2003). Said amendment amended the specification and Claim 29 and cancelled Claim 73. Thus, Claims 9-25, 28-31, 54-59, 61, 63-67, 69-72, 76-87, and 96-99 are pending in the instant application and will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority of U.S. Application Nos. 08/740,682, filed on November 1, 1996, and 09/297,418, filed on April 30, 1999. It is noted that continuation-in-part benefit of both U.S. applications is claimed and the pending claims may not be afforded priority back to the earliest effective filing date in each case.

Drawings

3. As previously noted, the drawings have been approved by the Draftsmen and are entered as formal drawings acceptable for publication upon the identification of allowable subject matter.

Compliance with the Sequence Rules

4. In response to the previous requirement to comply with the sequence rules (Paper No. 27, paragraph 4), Applicants appropriately amended the specification on pages 49-54 to assign SEQ ID NOs to all described sequences. Thus, the instant application now fully complies with the sequence rules.

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Withdrawn - Objections to the Specification

5. Previous objection to the specification for being confusing with respect to the sequence listing is withdrawn by virtue of Applicants' amendment noting each of the 74 sequences in the sequence listing in the description.

Maintained - Objections to the Specification

6. Previous objection to the specification for being confusing on page 8 is maintained. Applicants' amendment to the specification does not clarify paragraph. As amended on February 12, 2003 (Paper No. 28), the paragraph discusses "organisms" that are modified. However, the specification extensively discusses polypeptides from these organisms that have been modified, not the organisms themselves. Appropriate clarification is required. The Examiner suggests replacing "The following organisms may be modified according to the methods and figures in the specification: *Hordeum vulgare*..." with ---CI-2 like polypeptides from various organisms may be modified according to the methods and figures in the specification, such as from *Hordeum vulgare* (SEQ ID NO:35),...---

Withdrawn - Objections to the Claims

7. Previous objection to Claims 10, 23, 56, 69, and 85 (and dependent Claims 11, 12, 14-18, and 96) for having an improper Markush group is withdrawn by virtue of Applicants' argument that the language is proper alternative Markush-type language.

8. Previous objection to Claim 73 under 37 C.F.R. § 1.75 as being a substantial duplicate of Claim 64 is withdrawn by virtue of Applicants' cancellation of said claim.

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Maintained - Objections to the Claims

9. Previous objection to Claims 13, 20, 24, 71, and 86 is maintained. In Claims 13 and 20, the proper structure for the alternative Markush language contains commas, and not semi-colons as pending, between the members of the group. In Claims 24, 71, and 86, no punctuation between the two members of the group is appropriate. Appropriate correction is required.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

10. Previous rejection of Claim 29 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "conservative substitution" is withdrawn by virtue of Applicants' amendment to ---conservatively substituted polypeptide--- as suggested by the Examiner. Moreover, on page 10, lines 20-25 of the specification as originally filed, the term "conservatively substituted" is clearly defined.

Maintained and New - Claim Rejections - 35 U.S.C. § 112

11. Previous rejection of Claim 99 under 35 U.S.C. § 132 and 35 U.S.C. § 112, first paragraph, new matter, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants argue that a limitation of "15-25 mole % lysine" in the claims is encompassed by a recitation of "15-35 mole % lysine" as originally filed. This is not found persuasive since the concept of the invention is clearly different in scope between the limitation added later and that which was originally filed. A polypeptide with the range of 15-25 mole % lysine was not considered the invention at the time of filing; only a polypeptide with the range of 15-35 mole % lysine was envisioned. Nowhere is it even implied that intermediate ranges were also envisioned at the time of filing.

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Additionally, the Examiner notes that no where in the specification is "15.00-25.00 mole % lysine" (emphasis added) described. These significant digits were added post filing in an attempt to overcome prior art rejection(s) (see below). This kind of precision was not described in the specification as originally filed.

In light of this consideration of the difference between the limitations "15.00-25.00" and "15-25", the instant new matter rejection is extended to include Claim 98. Thus, Claim 98 is rejected under 35 U.S.C. § 132 and 35 U.S.C. § 112, first paragraph, new matter, for the phrase "15.00-30.00 mole % lysine" for the reasons noted above related to the precision of the range. A range of 15-35 mole % lysine is supported, but a range of 15.00-30.00 mole % lysine is not.

Maintained - Claim Rejections - 35 U.S.C. § 102

12. Previous rejection of Claims 98-99 under 35 U.S.C. § 102(b) as being anticipated by Kleber-Janke *et al.* is conditionally maintained – the condition being that a limitation of ---15-30--- and not "15.00-30.00" is being read into the claims based on the new matter rejections above. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicants argue that the polypeptide of Kleber-Janke *et al.* does not meet all the limitation of the claim. Firstly, it is argued that the polypeptide of Kleber-Janke *et al.* is not "modified". This is irrelevant since the way the product is produced does not exclusively define the product if it can be produced by an alternate method, which is the case here – a product is a product no matter how it was made, unless Applicants can show that a polypeptide that has undergone modification is somehow different from a naturally occurring polypeptide with the

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same structural characteristics as claimed. The second argument concerning the difference between 14.7 mole % and 15.00 mole % is held in abeyance as noted above due to the new matter rejection; this argument would be considered valid if the new matter rejection above is withdrawn. Lastly, Applicants argue that the sequence identity is based on only a portion of the sequence. This is not convincing because the sequences, when considered as a whole, are as follows:

Kleber-Janke <i>et al.</i>	68 amino acids	32 matches to SEQ ID NO:2
SEQ ID NO:2	83 amino acids	32 matches to Kleber-Janke <i>et al.</i>

Thus, SEQ ID NO:2 is $32/83 \times 100 = 38.55\%$ (rounded up to 39%) identical while the claims require only 30% identity.

As previously mentioned, the Examiner notes that Applicants have previously argued analogous rejections based on the priority date that should be afforded to the instant subject matter. Applicants have argued that this subject matter deserves priority back to application 08/740,682, filed on November 1, 1996 (which the instant application is a continuation-in-part of). This application is currently unavailable in the publication division awaiting patenting. If Applicants' assessment that 08/740,682 discloses the invention in Claims 98-99 is concurred by the Examiner, the instant rejection will be withdrawn.

Summary of Issues Pending

13. The following is a summary of the issues pending in the instant application.
 - a) The specification stands objected to for being confusing on page 8.
 - b) Claims 13, 20, 24, 71, and 86 stand objected to for having an improper structure.
 - c) Claims 98 and 99 stand rejected under 35 U.S.C. § 132 and 35 U.S.C. § 112, first paragraph, new matter.
 - d) Claims 98-99 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Kleber-Janke *et al.*

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Conclusion

14. Claims 9-25, 28-31, 54-59, 61, 63-67, 69-72, 76-87, and 96-99 are pending. Claims 13, 20, 24, 71, and 86 are objected to. Claims 98-99 are rejected. Claims 9-12, 14-19, 21-23, 25, 28-31, 54-59, 61, 63-67, 69, 70, 72, 76-85, 87, and 96-97 are allowed.

The instant Office action is **NON-FINAL** based on the newly presented new matter rejection of Claim 98 herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK
April 8, 2003

